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# Nutritional interventions for preventing stunting in children (0 to 5 years) living in urban slums in low and middle-income countries (LMIC) (Protocol)

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## TABLE OF CONTENTS

[Intervention Protocol]

# Nutritional interventions for preventing stunting in children (0 to 5 years) living in urban slums in low and middle-income countries (LMIC)

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## ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

Primary objective

To assess the impact of nutritional interventions to reduce stunting in children under five years old in urban slums.

Secondary objective

To assess the effect of nutritional interventions on other nutritional (wasting and underweight) and non-nutritional outcomes (socioeconomic, health and developmental) in addition to stunting.

## BACKGROUND

Globally, more than one in four children under the age of five years is too short for their age. Sub-Saharan Africa and South Asia suffer the heaviest burden, with 75% of the world's stunted children ( UNICEF 2013). Low height-for-age or stunting reflects a failure to reach a minimal stature associated with current and future healthy development and is a key indicator of chronic undernutrition. Stunted children suffer from impaired growth with permanent consequences in their adult life, and face a high risk of morbidity and mortality (Black 2008; Dewey 2011; Grantham-McGregor 2007; McDonald 2013; Victora 2008).

Poverty and poor living conditions are associated with stunting. In 2012, approximately 33% of urban residents in the developing world lived in slums and by 2030 slum populations of less developed countries are expected to reach two billion people (UNITED NATIONS 2012). Every day, more than 100,000 people move to slums in the developing world. Nearly 1.5 billion people currently live in urban slums without adequate access to health care, clean water and sanitation (BRC 2012). Evidence shows that children living in slums are more likely to suffer from undernutrition, including stunting, than children living elsewhere in the city (Awasthi 2003; Ghosh 2004; Haddad 1999; Hussain 1999;

Menon 2001; Pryer 2002; Ruel 1999; Unger 2013). While efforts towards reduction of stunting have succeed globally (Lundeen 2014), and in Ethiopia and in Mahrastrata state, India (Haddad 2014), in sub-Saharan Africa and South Asia, stunting rates have unfortunately remained largely static (Bhutta 2013). Achieving 2025 WHO global health targets to reduce stunting by 40% in children under five years old will depend on continuous efforts to prevent stunting within slums.

## Description of the condition

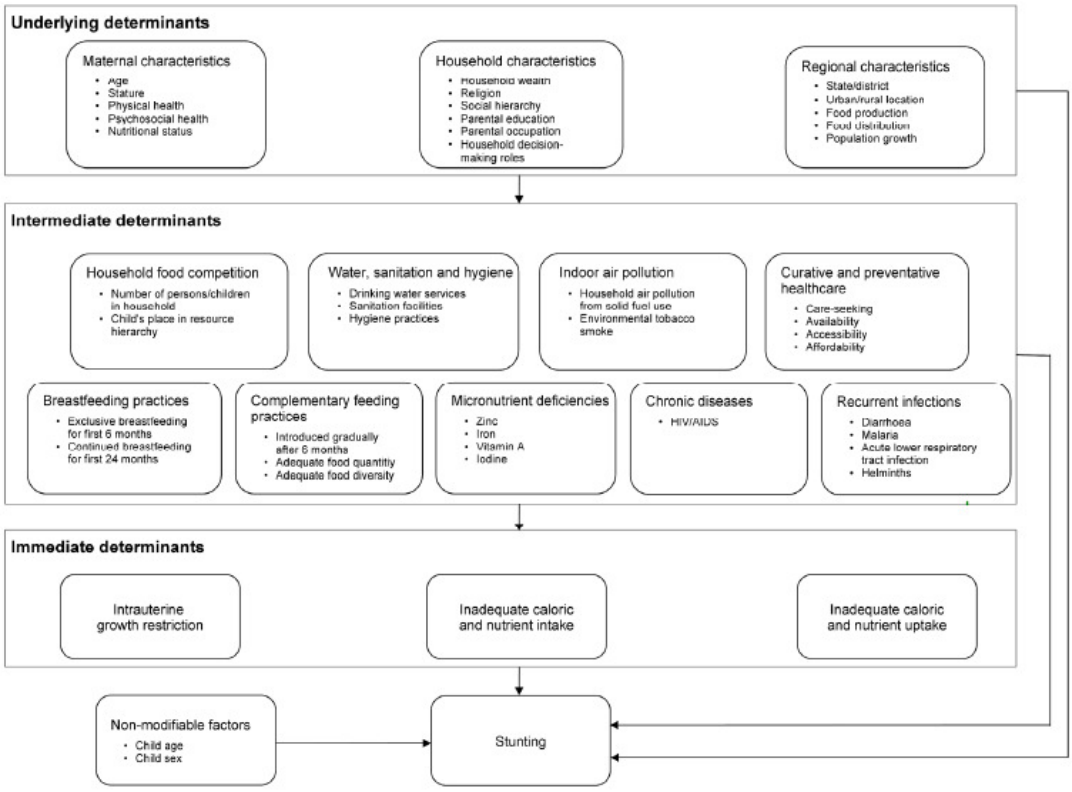
Stunting reflects chronic undernutrition during the most critical periods of growth and development in early life. Stunting in children can be assessed by physical growth performance through anthropometry. Growth faltering happens mostly from three months to 18 to 24 months of age (Victora 2010). The prevalence of stunting increases very rapidly between 12 to 24 months (40% to 54%), continues increasing until 36 months of age (58%), and then remains fairly stable until five years old (55%) (Bhutta 2013).

### Diagnosis and causes

Stunting is defined as the percentage of children aged 0 to 59 months whose height-for-age is below minus two standard deviations for moderate and minus three standard deviations for severe stunting from the median of the 2006 WHO Child Growth Standards (UNICEF 2013).

The causes of stunting are multi-sectorial and multifactorial, as shown in Figure 1 including food, health and care practices, and are classified as immediate (individual level), intermediate (individual/household level) and underlying (maternal, household and regional characteristics). The immediate causes of stunting are intrauterine growth retardation, inadequate nutrition after the recommended period of exclusive breastfeeding for the high demand of nutrient and frequent infections during early life (Frongillo 1999; Shrimpton 2001; Victora 2010). Figure 1 shows a model by Fenske 2013, which conceptualised the causes of stunting in India. It used regression analysis to model the effects of determinants for stunting. Although this conceptual framework considers infections as intermediate causes, we will consider them in this review as immediate based on the work by Frongillo 1999, Shrimpton 2001, Victora 2010, Black 2013 and Bhutta 2013. Driving these immediate causes are intermediate and underlying causes including food security, childcare practices, maternal education, access to health services and water, hygiene and sanitation conditions. Ultimately, these factors are embedded in the larger political, economic, social and cultural environment (Bogin 2014). In Fenske's model (Fenske 2013), child age and sex are considered the non-modifiable risk factors and, with household wealth and maternal education, showed the largest effects on stunting.

**Figure 1. Conceptual framework of stunting (source: Fenske 2013)**




Children are typically screened as stunted in the first two years of life (Victora 2010). However, the process for a child becoming stunted is determined by the cumulative effects that span across generations. Even before the child is conceived, if his/her mother has previously suffered nutritional insults, this can have detrimental impacts on her children (Victora 2010). This relates to the intergenerational influence hypothesis that malnutrition of the mother during her fetal and early postnatal development has health consequences for her offspring, especially low birth weight and obesity (Barker 1990; Barker 1995; Bogin 2007; Drake 2004; Gluckman 2004; Kuzawa 2005; Kuzawa 2007; Varela-Silva 2009). Similarly, for the child, the process of becoming stunted starts *in utero* when pregnant women suffer from nutrient deficiencies and other nutritional insults (Dewey 2011).

To explore the root causes of children's undernutrition in the context specific to urban settings, we conducted a scoping review that also assessed the impact of risks factors on children's undernutrition (Goudet 2014). This scoping review found that the mother's education was the most reported factor associated with the child's stunting, followed by the child's age, the child's gender, household income, family size and the child's morbidity status. These findings were similar to those reported by Fenske 2013. In urban settings, the mother's education may be even more important for nutritional status than in other contexts as educational attainment can be linked to the ability of mothers to make choices in caring practices (Unger 2013). In terms of age, the reported age groups with the highest prevalence of stunting were: 36 to 47 months (Olack 2011), and 48 to 60 months (Alam 2011). The study by Alam excluded those under 24 months and focused on 24- to 60-month olds. Analysis by gender showed that boys were more at risk than girls. Low household income was identified as a risk factor and is also well known to be an underlying cause of stunting. In urban settings, the dependence on cash flow aggravates the importance of household income. On family size, there are conflicting results with two studies finding that living in a small family was a predictor of stunting (Mian 2002; Veiga 2010), while two studies found the opposite (Neervoort 2013; Shit 2013; Singh 2011). Finally, in terms of morbidity, diarrhoea was the most reported type of illness associated with stunting.

## Consequences of stunting

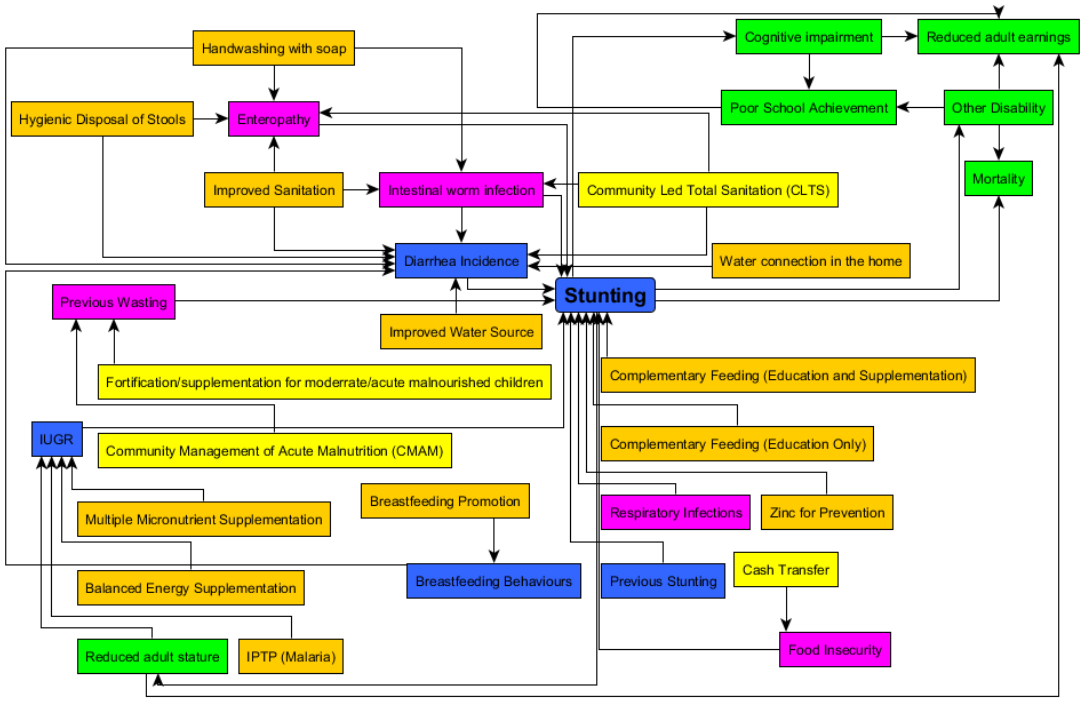
The vicious cycle of undernutrition and disease means that stunted children are more likely to become sick due to their immunodeficiency status and sick children are more likely to become stunted due to poor nutrient absorption (UNICEF 2013). A severely stunted child faces a 5.5 times higher risk of dying than a normal child (McDonald 2013). In terms of disability and mortality burden, stunting in children 36 months or older contributes to about 9.4 million Disability Adjusted Life Years (DALYs) (Bhutta 2013). In the long term, stunting in children may affect adult size, intellectual ability, poor school achievement, poor school performance, economic productivity and reproductive ability, and may increase the risk of metabolic disorders and cardiovascular disease (Black 2008; Dewey 2011; Grantham-McGregor 2007; Victora 2008). The fact that stunted children are likely to develop obesity and other chronic diseases in their adult life places them at even greater risk in transitional countries experiencing increasing urbanisation and shifts in diet and lifestyle. The consequences of nutritional transition in urban settings create economic and social challenges in many low- and middle-income countries where stunting is prevalent, especially among poorer population groups (UNICEF 2013). This nutritional transition will contribute to the intergenerational malnutrition cycle with the youngest generation born of obese or overweight mothers being again at higher risk of being malnourished (Varela-Silva 2012).

A window of opportunity to prevent long-lasting consequences of stunting exists in the first 1000 days of a child's life (the first two years of a child's life and the nine months of life in their mother's womb) (Bhutta 2008; UNICEF 2013; Victora 2008). Long-term consequences of stunting can be averted or minimised in adult life if it is prevented within this timeframe (Bhutta 2008; UNICEF 2013; Victora 2008). There is a limited opportunity for catch-up growth during adolescence because stunted children often experience a delay in skeletal maturation, lengthening the total period of time for growth in height (Dewey 2011; Martorell 1994). Even so, the height deficits experienced by the age of seven years are often greater than any possibility for growth recovery during adolescence (Bogin 1992).

## Description of the intervention

Reductions in stunting can be achieved through evidence-based interventions. In the maternal and child undernutrition *Lancet* series (2008) clear evidence was found for a set of interventions that are successful in promoting children's health (Bhutta 2008). Combining and scaling up 10 of these proven nutrition-specific interventions (the ones in blue in Figure 2) to 90% coverage could reduce stunting by 20%, which represents 33.5 million fewer stunted children (Bhutta 2013; Fenske 2013; Milman 2005; Remans 2011).

**Figure 2. Logic model showing direct linkages between stunting risk factors, intervention and mortality/disability (the model is inspired by LIST and purple boxes were added based on new evidence) (LIST 2014). Blue, or purple (new) are risk factors, orange or yellow (new) are interventions, green are consequences of stunting.**




Specifically, to tackle the direct causes of stunting, recommended interventions should focus on improving nutrition and prevent related diseases (Figure 2; LIST 2014). The logic model in Figure 2 shows how interventions can tackle the immediate causes of stunting: diarrhoea/enteropathy/intestinal worm infections, intrauterine growth restriction, breastfeeding behaviours, respiratory infections, previous wasting and previous stunting. This model has been designed based on the 'lives saved tool' for stunting and has integrated enteropathy, intestinal worm infections (Brown 2013; Black 2013; Keusch 2013; Keusch 2014; Lantagne 2014; Olofin 2013; Richard 2013), and previous wasting (Khara 2014), as additional risk factors based on the cited work (in purple). The related interventions have been added in yellow. The model has also been modified to integrate the consequences of stunting (presented in green colour) and new risk factors identified in our scoping review and previous literature have been added (in purple colour). Micronutrient interventions for children include strategies for supplementation of vitamin A (in the neonatal period and late infancy), preventive zinc supplements, iron supplements for children in areas where malaria is not endemic (in malaria endemic areas, iron supplementation can increase the risk of mortality) (Yakoob 2011), and universal promotion of iodised salt (Black 2013). Improvement of complementary feeding through strategies in food-secure populations such as nutrition counselling and in food-insecure populations nutrition counselling, food supplements, conditional cash transfers, or a combination of these, could substantially reduce stunting and the related burden of disease (Imdad 2011). Treatment interventions for acute malnutrition include community-based management of acute malnutrition (CMAM) and fortification/supplementation for moderate acute malnourished children. Interventions to reduce the risk of Intra Uterine Growth Restriction (IUGR) include Intermittent Preventive Treatment of malaria during Pregnancy (IPTP), use of insecticide-treated bed nets for pregnant women (Ishaque 2011), multiple micronutrient supplementation and balanced energy protein supplementation for pregnant women who are food insecure (Imdad 2011). To reduce the risk of the effect of diarrhoea/enteropathy on stunting (Checkley 2008), interventions include water, sanitation and hygiene (WASH) interventions (e.g. improved water sources, water in the home, improved sanitation, handwashing with soap, disposal of faeces and community-led total sanitation) (Cairncross 2010; Cairncross 2006), as well as promotion of op-

timal breastfeeding practices (Black 2013; Lamberti 2013). Cash transfer can have an impact on children's nutrition and can lead to a reduction in stunting in food-insecure households (Bangladesh) (Mascie-Taylor 2010).

In the context of urban slums, the scoping review found that the interventions tackling children's stunting status were: 1) nutritional interventions (supplementation, micronutrient fortified food or complementary food, promotion of nutrition), 2) health interventions (Reproductive and Child Health (RCH) immunisation, and increased access to health services with performance pay), 3) WASH interventions (sanitation programmes and community-based handwashing programmes), and 4) safety net programmes (conditional cash transfer) (Table 1).

**Table 1 - Findings from scoping review (children under five years old, stunting as an outcome)**

| Authors | Study title | Study location | Study design | Intervention type |
|---|---|---|---|---|
| Attanasio 2005 | 'The short term impact of a conditional cash subsidy on child health and nutrition in Colombia' | Colombia | Randomised controlled trial (RCT) | Safety net - conditional cash transfer with nutritional transfer |
| Berger 2008 | 'Malnutrition and morbidity among children not reached by the national vitamin A capsule programme in urban slum areas of Indonesia' | Jakarta, Surabaya, Semarang, Makassar and Padang, Indonesia | Cluster-RCT | Nutrition - micronutrient supplementation (vitamin A) |
| Kiran 2011 | 'Influence of RCH programme on nutritional status and immunization status in urban slum children' | India | Cross-sectional study | Health - reproductive and child health (RCH) (immunisation, antenatal care, skilled attendance during delivery and treatment of common childhood illnesses) |
| Langford 2011 | 'Hand-washing, subclinical infections, and growth: a longitudinal evaluation of an intervention in Nepali slums' | Katmandu, Nepal | Non-RCT | WASH - community-based handwashing programme |
| Oelofse 2003 | 'Micronutrient deficiencies in South African infants and the effect of a micronutrient-fortified complementary food on their nutritional status, growth and development' | South Africa | RCT | Nutrition - micronutrient fortified complementary food |

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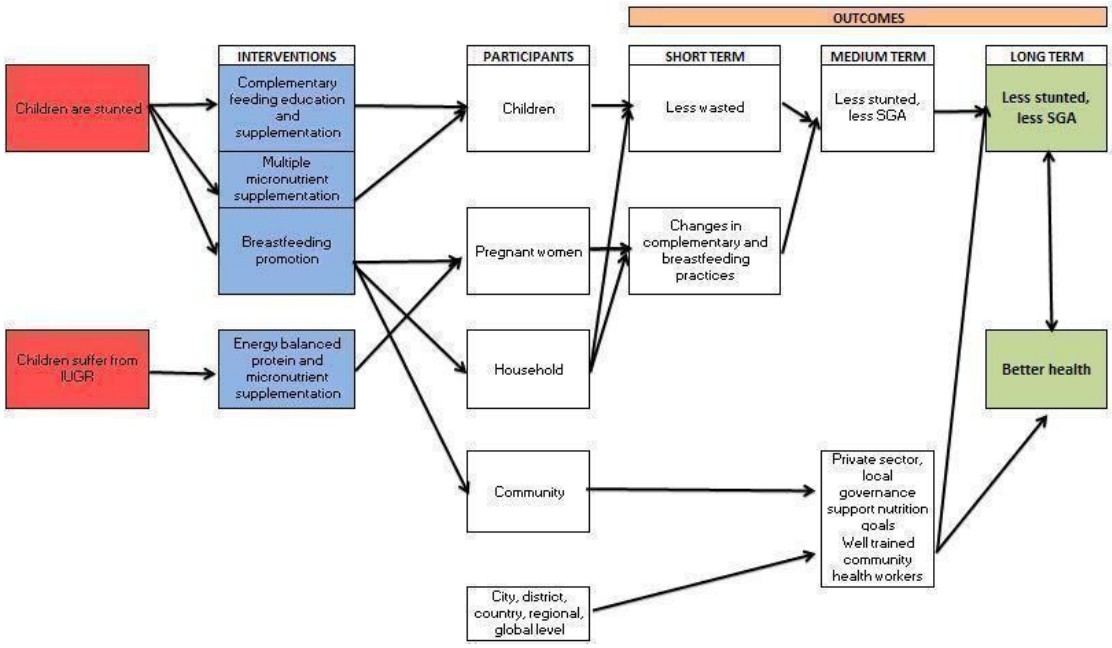
|---|---|---|---|---|
| Semba 2011 | 'Consumption of micronutrient-fortified milk and noodles is associated with lower risk of stunting in preschool-aged children in Indonesia' | Urban slums and non-urban slum areas, Indonesia | Cluster-RCT | Nutrition - micronutrient fortified milk and fortified noodles |
| Waihenya 1996 | 'Maternal nutritional knowledge and the nutritional status of preschool children in a Nairobi slum' | Kibera slum, Nairobi, Kenya | Cross-sectional study | Nutrition - promotion of nutrition |

## How the intervention might work

We created a conceptual model of how a nutritional intervention in urban settings might work (Figure 3). The model presents nutritional interventions that tackle determinants of stunting at the individual, household, community and country level, as evidence has shown that these level factors in an urban environment have an independent effect on children's health and nutritional status (Goudet 2011a, Goudet 2011b; Harpham 2009; Madise 1999; Milman 2005; Spears 2013; Unger 2013). The study by Milman 2005 demonstrated that factors at country level (initial and change in immunisation rate, initial and change in safe water rate, initial female literacy rate, initial government consumption, initial income distribution and the initial proportion of the economy devoted to agriculture) were independently associated with improvements in stunting. The study findings suggested that both interventions at country level and specific interventions at community/individual level were important. At the household level, determinants noted are socioeconomic status (SES), cultural and psychosocial factors that influence behaviours and childcare practices, food security (access to healthy food) and access to public services. At the community level, the determinants include local governance (capacity and ability), legal and political structures, employment opportunities, markets and willingness of the private sector to support nutrition goals. It is also key to determine the right level of intervention in order to maximise programme effectiveness. For example, sanitation upgrades were more effective in promoting child health when implemented in a clustered way rather then at an individual household level in an urban context (Bangladesh) (Buttenheim 2007). Interventions that aim to change social factors at a household or community level can contribute towards an enabling environment for improved child nutrition (Pridmore 2007; Pridmore 2010). Through promoting understanding and involving the community, community leaders and community-based organisations can be encouraged to grasp issues related to land tenure and people's rights in order to develop successful programmes (BRC 2012; Ghosh 2004). Approaches to delivering interventions can involve governmental or non-governmental agencies undertaking broad-scale programmes, or community-based initiatives that use community resources internal to the slums (Ernst 2013). Both of these strategies may involve fundamental infrastructure changes and include improving housing structure, developing roadways, and access to water and sanitation, which have an impact on children's health. Interventions that work to effect more immediate change in health outcomes include improved access to quality health care and improving the quality of local schools and the training of community health workers (Ernst 2013). A notion of time has been integrated to reflect how to eliminate stunting in the long run. These interventions should be supplemented by improvements in the intermediate and underlying determinants of stunting by creating an enabling environment and a political will towards stunting reduction.

**Figure 3. Logic model of nutritional intervention tackling stunting in an urban setting**




## Why it is important to do this review

The proposed review is informed by the findings from the authors' scoping review, which confirmed the value of undertaking a full systematic review. The results for the interventions, although limited (21 studies eligible with only 15 using stunting as an outcome), were useful in mapping the interventions in nutrition, health, WASH and safety net programmes classification. We were able to extract from most studies enough information to show nutritional outcome and to measure effectiveness. It helped to identify the appropriate Population, Intervention, Comparison and Outcome (PICO) parameters for this systematic review (Table 2). We concluded that it would be useful to conduct a full systematic review specific to nutritional interventions only, with a more detailed search strategy, to assess the quality of the studies and to conduct meta-analyses to calculate and compare the effect of nutritional interventions on children's nutritional health. In our proposed Cochrane review, the interventions have the specificity of targeting slum areas and stunting and therefore this review differs from those previously published in the *Lancet* series because of its geographical focus (we will also search new sources of published studies and cover recent work since 2012 - the *Lancet* systematic review ended in 2011).

**Table 2 - Parameters informed by the scoping review**

| Parameters | Scoping review | Recommendations for Cochrane review |
|---|---|---|
| Type of studies | The studies included 12 randomised controlled trials, 33 cross-sectional studies, 1 case study and 11 cohort studies | We will include randomised (including cluster-randomised) and quasi-randomised trials with either individual or cluster randomisation, and non-randomised controlled trials, controlled before and after studies (cohort or cross-sectional), interrupted time series (ITS) and historically controlled studies |
| Population | More than half of the studies (51%) focused on children under 5 years of age | We will focus on children under 5 years old. Research has shown that it is key to intervene in children's stunting as early as possible in a child's life (fetus up to 24 months old). As only 19% of the studies focused on children |

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| | | |
|---|---|---|
| | | under 2 years old, the under 5 years range is preferred |
| Intervention | All of the interventions were nutrition-specific or -sensitive with nutritional intervention being the most dominant type (76%): school feeding, supplementation/fortification and nutrition promotion. The rest of the interventions were health (14%), WASH (9%) and safety net (1%). Only 71% of the interventions were assessed as effective | As nutritional intervention was the most reported type, we will limit the parameter to this category |
| Comparison | The comparison groups were either: control, no control, intervention or rural areas | We would like to exclude comparisons with rural areas as we feel that it will not help us to draw conclusions in terms of programmatic implications. These studies are typically nutritional surveillance programmes with children randomly sampled at one time point. Consequently the intervention duration and the change in anthropometric measurements are not taken into consideration. We will include comparison with another intervention if the study is comparing the same intervention in the two areas. This can show the added benefits of a combined intervention; for example, a complementary feeding education intervention versus a complementary feeding education intervention + nutrition promotion |
| Outcome | The outcome measures were mainly stunting, underweight and wasting using weight-for-height, height-for-age and weight-for-age z-scores respectively and/or prevalence and/or mean using National Center for Health Statistics (NCHS), World Health Organization (WHO) and Indian Association of Paediatrics (IAP) growth standards and references as defined below:<br>• The National Center for Health Statistics (NCHS) growth reference: they were formulated in the 1970s by combining growth data from 2 distinct data sets, which were originally planned to serve as a reference for the USA. They were used from the late 1970s until the WHO growth standards (2006) were published<br>• The World Health Organization (WHO) growth standards: they were published in 2006 and developed a new international standard for assessing physical growth, nutritional status and motor development in all children from birth to age 5<br>• The Indian Association of Paediatrics (IAP) classification: it is based on weight-for-age, % of the median (normal > 80; grade I - mild 71 to 80; grade II - moderate 61 to 70; grade III - severe 51 to 60; grade IV - very severe < 50) using the Harvard growth references (1966) | We will use stunting only operationalised as height-for-age z-score. We will use the change in z-score to compare the impacts of intervention between studies as the use of NCHS, WHO and IAP growth standards and references makes the outcomes hard to compare. Indices, anthropometric measurements and change in anthropometric measurement will be included. We will not include measurement of micronutrient deficiencies as the literature is too limited (only 2 studies) |

We also identified a range of systematic reviews that overlap with this review. While evidence exists from these reviews, there is a need to review the evidence to identify the nutritional interventions that meet this review's PICO parameters and to present an overview of the interventions that work in urban settings to promote children's nutrition. Thus, this review will build on, add to and complement the following reviews. In the Turley 2013 review, the focus is on infrastructural interventions in slums and their health impact. There was a limited but consistent body of evidence to suggest that slum upgrading may reduce the incidence of diarrhoeal diseases and water-related expenditure. Two studies were identified under nutritional deficiencies in slum settings and would be relevant to this review. Mori 2012 assessed zinc supplementation for improving pregnancy and infant outcome and included one study in urban slums. In De-Regil 2011, the effect of home fortification of foods with multiple micronutrient powders was evaluated for health and nutrition in children under two years of age. This review included one study in urban settings. In Sguassero 2012, community-based supplementary feeding interventions for promoting the growth of children under five years of age in low- and middle-income countries were analysed and the findings showed that this intervention had a negligible impact on child growth, which should be interpreted with caution due to the high heterogeneity of the studies. One study in urban slums was included. The review underway by De-Regil will assess point-of-use fortification of foods with micronutrient powders containing iron in children of preschool and school age (De-Regil 2012).
From the combined results of the systematic reviews and the overview of existing evidence, we will be able to draw conclusions by assessing the impact of nutritional intervention on stunting in the context of the urban slum environment.

# OBJECTIVES

## Primary objective

To assess the impact of nutritional interventions to reduce stunting in children under five years old in urban slums.

## Secondary objective

To assess the effect of nutritional interventions on other nutritional (wasting and underweight) and non-nutritional outcomes (socioeconomic, health and developmental) in addition to stunting.

# METHODS

## Criteria for considering studies for this review

### Types of studies

We will include a variety of study designs in this review based on the criteria set down by the Cochrane Effective Practice and Organisation of Care (EPOC) Group:

- Randomised (including cluster-randomised) trials: any experimental design where stunted children are allocated to one or other of the interventions, e.g. micronutrient supplementation or complementary feeding education.
- Quasi-randomised trials with either individual or cluster-randomisation: we will include studies with at least two intervention sites and two comparator sites.
- Non-randomised controlled trials: we will include studies with at least two intervention sites and two comparator sites.
- Controlled before and after studies (cohort or cross-sectional): the timing of the period of the study in both the intervention and comparator should be comparable. Pre- and post-intervention periods of measurement of both groups will be the same. Both groups will be comparable for key characteristics.
- Interrupted time series (ITS) (according to EPOC standards): studies with a clearly defined point in time when the intervention occurred; these studies must have at least three data points, one before and two after the intervention began and with a control group in a different site with no intervention.
- Historically controlled studies: studies with repeated measures made in stunted children at each time point and with a control group in a different site with no intervention.

### Types of participants

Children from low- and middle-income countries (LMIC), from birth to five years old, living in urban slums.
We are considering in this review low-income informal settlements or slums as defined by UNHABITAT 2004 as lacking one or more of the following: 1) access to improved water (adequate quantities of water that is affordable and available without excessive physical effort and time), 2) access to improved sanitation (access to an excreta disposal system, in the form of a private or public toilet, shared with a reasonable number of people), 3) security of tenure (evidence of documentation that can be used as proof of secure tenure status, or for protection from forced evictions), 3) durability of housing (permanent and adequate structure in a non-hazardous location, protecting its inhabitants from the extremes of climatic conditions such as rain, heat, cold or humidity), 4) sufficient living area (not more than three people sharing the same room). We will include studies that specify the location as being a slum assuming that this is meeting the UNHABITAT definition criteria. We will also include studies that do not specify the location as being a slum but do provide detailed description of the location enabling us to classify it as a slum or not based on the UNHABITAT definition criteria. We will include studies conducted in urban slums and/or semi/peri-urban slums. We will include studies conducted in urban areas considered as deprived or taking into account poverty

level.

We are considering low- and middle-income countries, defined as those with a gross national income (GNI) per capita, calculated using the *World Bank Atlas* method:

- for low-income countries: a GNI per capita of USD 1045 or less in 2013;
- for middle-income countries: a GNI per capita of more than USD 1045 but less than USD 12,746 (World Bank 2014).

## Types of interventions

Based on the scoping review discussed in earlier sections (Table 1), the following interventions are considered for this review:

- Nutritional interventions (e.g. counselling in feeding practices, maternal dietary or micronutrient supplementation; promotion of optimum breastfeeding; complementary feeding and responsive feeding practices and stimulation; dietary supplementation; diversification and micronutrient supplementation or fortification for children).
- Comparator: controls will include either treatment, intervention or placebo.
- Combined approach programmes (e.g. zinc supplementation + home-based nutrition counselling intervention) only if the other co-interventions are the same in both the intervention and comparison groups.
- Interventions at an individual and community level (slum).

We will exclude the following interventions:

- We will exclude treatment interventions for severe and moderate acute as opposed to chronic malnutrition if implemented as a single intervention. These are community-based management of acute malnutrition (CMAM) for severe acute malnourished children (SAM), inpatient treatment of SAM children or fortified food for moderate acute malnourished (MAM) children. As wasting is considered as a risk factor for stunting, we will include these interventions only if combined with other interventions to maximise the chances of the combined effects on linear growth.
- Comparisons with rural areas as explained in Table 1.

## Types of outcome measures

We will include studies reporting on primary outcomes and studies reporting on primary and secondary outcomes. We will not include studies reporting on secondary outcomes only.

### Primary outcomes

Stunting as measured by anthropometry (Table 3):

- Height expressed in cm or height-for-age z-score.
- Low birth weight (as birth length is not usually available, birth weight serves as a proxy for small size at birth, itself a proxy for inadequate fetal nutrition and growth).

We will compare these measures in terms of:

- height gain during the intervention;
- change in malnutrition indices (height-for-age below -2 standard deviations and/or -3 standard deviations) during the intervention;
- change in z-score during the intervention.

We will include studies using IAP, WHO growth standards and NCHS references as explained in Table 1. The nutritional outcomes will be followed up post intervention. We will not limit the follow-up period as interventions to tackle stunting can have effects that span a lifetime.

**Table 3: Definition and explanation of anthropometric indicators, height-for-age, weight-for-age, weight-for-height, low birth weight, mid-upper arm circumference (MUAC) and triceps skin fold thickness** (UNICEF 2013)

| |
|---|
| **Height-for-age (HFA):** Height-for-age measures linear growth. A child who is below two standard deviations (-2 SD) from the median of the WHO Child Growth Standards in terms of height-for-age is considered short for his/her age, or stunted. This condition reflects the cumulative effect of chronic malnutrition. If a child is below minus three standard deviations (-3 SD) from the median of the WHO Child Growth Standards, then he/she is considered to be severely stunted. Stunting reflects a failure to receive adequate nutrition over a long period of time and is worsened by recurrent and chronic illness. Height-for-age, therefore, reflects the long-term effects of malnutrition in a population and does not vary appreciably according to recent dietary intake |
| **Weight-for-height (WFH):** Weight-for-height describes current nutritional status. A child who is below two standard deviations (-2 SD) from the median of the WHO Child Growth Standards for weight-for-height is considered to be too thin for his/her height, or wasted. This condition reflects acute or recent nutritional deficit. As with stunting, wasting is considered severe if the child is more than three standard deviations below the reference median or by a mid-upper-arm circumference less than 115 mm with or without nutritional oedema. In the presence of bilateral pitting oedema, the term kwashiorkor is used. Severe wasting is closely linked to mortality risk |

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| |
|---|
| **Weight-for-age (WFA):** Weight-for-age is a composite index of weight-for-height and height-for-age. Thus, it does not distinguish between acute malnutrition (wasting) and chronic malnutrition (stunting). A child can be underweight for his age because he/she is stunted, because he/she is wasted, or both. Children whose weight-for-age is below two standard deviations (-2 SD) from the median of the WHO Child Growth Standards are classified as underweight. Children whose weight-for-age is below three standard deviations (-3 SD) from the median of the WHO Child Growth Standards are considered severely underweight. Weight-for-age is a good overall indicator of a population's nutritional health |
| **Low birth weight (LBW):** LBW is defined as a weight of less than 2500 grams at birth |
| **Mid-upper arm circumference (MUAC)**: measures the muscle mass of the upper arm. A flexible measuring tape is wrapped around the mid-upper arm (between the shoulder and elbow) to measure its circumference. MUAC should be measured to the nearest 0.1 cm. MUAC is a rapid and effective predictor of risk of death in children aged 6 to 59 months and is increasingly being used to assess adult nutritional status |
| **Triceps skin fold thickness**: is used to estimate body fat, measured on the right arm halfway between the olecranon process of the elbow and the acromial process of the scapula |

#### Secondary outcomes

The secondary outcomes are prioritised as nutritional outcomes first and non-nutritional outcomes second.
Child nutritional status as measured by anthropometry (Table 3):

- Weight expressed in kg or WFA z-score
- Weight and height combined and expressed in WFH z-score
- MUAC, triceps skin fold thickness expressed in mm

We will compare these measures in terms of:

- height or weight gain during the intervention;
- change in malnutrition indices (WFA and WFH below -2 standard deviations and/or -3 standard deviations) during the intervention.

Non-nutritional outcomes such as health, socioeconomic and developmental:

- Health measured by: diarrhoea, acute respiratory infection, measures of physical well-being (e.g. Harvard Step Test), deaths.
- Socioeconomic, measured by at least one of the following: household income; household assets; households above or below poverty threshold; employment and occupation. Developmental (cognitive, mental and motor skill) as defined by trialists (e.g. the Bayley Scales of Infant Development Bayley Mental Development Index, Bayley Psychomotor Development Index, Stanford-Binet Test, DENVER II Developmental Screening Test).
- Any potential negative or positive effects associated with the intervention, such as increased undernutrition/diarrhoea or improved nutritional status in the siblings.

We will group the outcome time points as follows: immediately post end of the intervention, one to six months post end of intervention, seven to 12 months after the end of the intervention. In case of age group point, we will group based on age (e.g. at birth, at one year old and at three years old).

## Search methods for identification of studies

The review will use a sensitive search strategy for electronic bibliographic databases, bibliographies of included articles and grey literature sources. We will contact the research Technical Advisory Group (TAG) members to identify additional published and unpublished references. The TAG formed of experts in the fields of urban health, nutrition and vulnerabilities is responsible for providing guidance and ensuring that evidence-based recommendations are disseminated widely and, where possible, implemented (detailed here http://nutritionways.org/research/tag/). Specifically for this systematic review, the TAG will act as a review advisory group as detailed here (http://ph.cochrane.org/Files/advisory%20group%20guidance_final.doc) (see section RAG page 28). We will conduct the search in English and French as it is expected that some publications from Africa may be written in French only. The search will include all publications from 1990 up to the present. Findings from publications before 1990 may be out of date in the very rapid changing environment of the slums. Our review will look at the findings from these reviews and narrow down the results using our PICO inclusion criteria (children under five years old in urban slums in low- and middle-income countries). We will also contact the authors of the reviews underway to identify potential studies that can meet our PICO crite-

ria. Finally, we will review the literature on the same topic or on the gaps identified in the studies. We will do this with a focus on nutritional outcomes and by searching additional nutrition-specific databases and sources of literature including grey literature, nutrition technical websites and non-governmental organisation (NGO) websites with a strong expertise in nutrition. As these other sources of literature were not included in the previous reviews (Bhutta 2008; Bhutta 2013), we expect to identify new studies. We will also contact implementing organisations that may have unpublished studies from their programmes in urban slums, which was not done for the previous reviews.

### Electronic searches

We will use Boolean operators and Medical Subject Headings (MeSH) through the databases selected (Table 4).

**Table 4: Databases selected for review**

| Database | URL Links |
|---|---|
| Cochrane Central Register of Studies (CENTRAL) | http://www.thecochranelibrary.com/view/0/index.html |
| Cochrane Public Health Group Special Register | http://ph.cochrane.org/cphg-reviews-and-topics |
| PubMed | http://www.ncbi.nlm.nih.gov/ |
| Web of Science | http://apps.webofknowledge.com/ |
| Ovid MEDLINE | http://ovidsp.uk.ovid.com/ |
| Biosis Citation Index | http://apps.webofknowledge.com/ |
| MEDLINE | http://apps.webofknowledge.com/ |
| IBECS (English) | http://ibecs.isciii.es/cgi-bin/wxislind.exe/iah/online/?IsisScript=iah/iah.xis&base=IBECS&lang=i&form=F |
| EMBASE | https://www.embase.com/login |
| WORLDCAT (OCLC) | http://www.oclc.org/en-UK/home.html?redirect=true |
| CINAHL (EBSCO) | http://www.ebscohost.com/academic/cinahl-plus-with-full-text |
| Popline | http://www.popline.org/ |
| BIBLIOMAP | http://eppi.ioe.ac.uk/webdatabases/Intro.aspx?ID=7 |
| ZETOC | http://zetoc.mimas.ac.uk |
| WHO International Clinical Trials Registry Platform | http://www.who.int/ictrp/en/ |
| MetaRegister of Controlled Trials (mRCT) | http://www.controlled-trials.com/mrct |
| UNSCN | http://unscn.org/en/home/ |
| African Index Medicus | http://indexmedicus.afro.who.int/cgi-bin/wxis.exe/iah/ |

(*Continued*)

| | |
|---|---|
| ClinicalTrials.gov | http://www.clinicaltrials.gov/ |
| Global Health Library | http://www.globalhealthlibrary.net/php/index.php |
| WHOLIS - the WHO Library Information System | http://dosei.who.int/uhtbin/cgisirsi/Thu+Jul++5+16:26:22+MEST+2012/0/49 |
| Health Management ProQuest | http://search.proquest.com/advanced |
| Google Scholar | http://scholar.google.co.uk/ |
| Loughborough University Catalogue plus | http://www.lboro.ac.uk/library/ |

We will handsearch reference lists of eligible studies for any additional relevant articles. We will contact subject experts and study authors and will ask them to provide additional information and further relevant references.
We will perform the initial literature search in 2015.

### Searching other resources

Grey literature or combined sources (grey literature and academic literature) databases are presented in Table 5.
**Table 5: Databases of grey literature or combined sources selected for review**

| Database | URL Links |
|---|---|
| Grey literature report | http://www.greylit.org/library/search |
| Virtual health library | http://www.bireme.br/php/index.php?lang=en |
| Index Medicus for South-East Asia Region (IMSEAR) | www.hellis.org |
| Virtual Health Sciences Library (VHSL) | www.emro.who.int/HIS/VHSL/ |
| 3ie impact | http://www.3ieimpact.org/en/ |
| eLENA e-Library of Evidence for Nutrition Actions | http://www.who.int/elena/en/ |
| Global database on the Implementation of Nutrition Action (GINA) | https://extranet.who.int/nutrition/gina/ |
| Nutrition Landscape Information System (NLIS) | http://apps.who.int/nutrition/landscape/search.aspx |
| Urban humanitarian response portal | http://www.urban-response.org/ |

(*Continued*)

| | |
|---|---|
| African Population Health Research Centre (APHRC) | http://aphrc.org/publications/ |

For unpublished and ongoing studies, we will contact a list of experts and researchers working in the field. The list will include experts working in the organisations and international groups reported below. We will also search their websites.

- UN agencies: the World Health Organization (WHO) Department of Child and Adolescent Health and Development; the United Nations Children's Fund (UNICEF); the World Food Program (WFP); the World Bank (WB); the United Nations Standing Committee on Nutrition (UNSCN); the United Nations Refugee Agency (UNHCR).
- Technical bodies (nutrition): the Food and Nutrition Technical Assistance Project (FANTA-2); the Emergency Nutrition Network (ENN); the International Malnutrition Task Force (IMTF); the Humanitarian Practice Network (HPN); the Community-Based Management of Acute Malnutrition (CMAM) Forum; the Global Nutrition Cluster (GNC); the Global Alliance for Improved Nutrition (GAIN); Helen Keller International (HKI).
- Technical bodies (urban slums): UN-HABITAT; Slum Dwellers International (SDI); CitiesAlliances.
- Academic institutions: Centers for Disease Control and Prevention (CDC); the International Centre for Diarrhoeal Disease Research (ICDDR); the Institute of Child Health London (ICH); the London School of Hygiene and Tropical Medicine (LSHTM); the Institute of Tropical Medicine (ITP) Antwerp, Belgium; Jameel Poverty Action Lab (J-PAL); International Initiate for Impact Evaluation (3ie).
- International non-government organisations (NGOs) and related websites: Save the Children (STC); Doctors without Borders (MSF); Valid International; Concern Worldwide; Action Against Hunger (ACF); CARE; NutritionWorks; Medecins du Monde (MDM); Oxfam; Red Cross movement; WorldVision; BRAC; Plan; Family Health International; Global Communities; ALNAP; Reliefweb; Coordination Sud.
- National departments for international development and non-institutional donors: USAID; UK Department for International Development (DFID); Swedish International Cooperation Development Agency (SIDA); Danish International Development Agency (DANIDA); French agency for International Development (AFD); Comic Relief.

#### Conference proceedings and others

- Nutrition: Field Exchange: the Emergency Nutrition Network Magazine, International Nutrition Congress; International Conference on Nutrition, Nutrition and Nurture.
- LMIC: African Nutritional Epidemiology Conference (ANEC).
- Human/anthropological biology/nutrition/urban health: journals for which articles are not included in the databases searched.
- Public health conferences (e.g. American Public Health Association; European Public Health Association).
- Global: International Conference on Urban Health, World Congress of Epidemiology.

#### Reference lists

We will check the reference lists of all the eligible studies.
Search terms are included in Appendix 1.
The search strategy is based on one MeSH nutrition search term AND/OR one intervention search term AND/OR one context search term, OR one population search term. We will specifically design the search depending on the database requirements. An example of the search strategy for MEDLINE is presented in Appendix 1.

## Data collection and analysis

### Selection of studies

We will screen titles and abstracts of studies for inclusion and then retrieve the full text of potentially eligible studies for screening. We will independently apply the inclusion criteria to those retrieved publications. Sophie Goudet (SG) will screen all titles and abstracts and Paula Griffiths (PB) and Barry Bogin (BB) will assess half each. We will discuss any disagreements on study inclusion to reach consensus. If this is not possible, we will consult Nyovani Madise (NM). We will seek further information from the authors where papers contain insufficient information to make a decision about eligibility. We will include reasons for non-selection of the studies screened for inclusion. We will use section 1 - general information and 2 - study eligibility of the pre-standardised data extraction form adapted from the Cochrane Public Health Group's Data Extraction and Assessment Template (Appendix 2) to capture information from all screened studies. We will record necessary information about inclusion decisions in order to design a PRISMA flow chart and a table of 'Characteristics of excluded

studies'. We will use Mendeley version 1.10.3 @ Mendeley 2008-2014 as our reference management software.

### Data extraction and management

We will extract data from the included studies with the use of the pre-standardised data extraction form - section 3 to 8 (Appendix 2) (the form will be tested and adapted as necessary before using it). We will capture data in The Cochrane Collaboration's statistical software, Review Manager 5 (RevMan 2014). Two authors (SG, PG or BB) will independently do this. We will then cross-check the data. We will discuss any differences between the two data extraction sheets to reach a consensus or consult a third author (PG, BB or NM) if a consensus is impossible to reach. We will also contact study authors to obtain any missing information or to clarify unclear data by obtaining the original report. We will extract data relating to the following from all the included studies; some of the form headings and subheadings are included here for illustration purposes (for the complete form, refer to the pre-standardised data extraction form included in Appendix 2):

- Section 3: Study details
  - Aims
  - Location
  - Delivery: community-based/primary health care/secondary health care/direct
  - Funding source, budget, implementing partner; design, integration within existing government health
  - Setting: delivered in humanitarian crisis/disaster or development; characteristics, squatter settlement, legal, dilapidated and change in living conditions (improving or worsening)
  - Duration of intervention
  - Sample size and unit of randomisation

- Section 4: Participants
  - Population: children data (age, sex), socioeconomic data, baseline anthropometry
  - Comparison group: children data (age, sex), socioeconomic data, baseline anthropometry

- Section 5: Intervention + co-intervention group/comparison group
  - Classification of the intervention
  - Context: food security, slum size, location, exposure to flooding, eviction, fire
  - Intervention type and components:
    - Type: micronutrient supplementation, complementary feeding

- Section 6: Outcomes

We will extract data pertaining to the primary and secondary outcomes defined earlier. For secondary outcomes, we will include any of the prioritised outcomes (nutritional or non-nutritional).

- Section 7: Results
  - We will extract data from each type of study design (e.g. RCT, controlled before and after (CBA), etc.) that we are including in this review
  - Other information
  - Recommendations: we will collect data on authors' potential recommendations based on the study results
  - Limitations: we will collect data on study limitations

- Section 8: 'Risk of bias' assessment

We will extract data on risk of bias using the Cochrane EPOC Group's guidance for assessing risk of bias for studies with a separate control group (RCTs, CCTs, CBAs) and risk of bias for interrupted time series (ITS) studies.

### Assessment of impact on equity

We will address aspects highlighted by the PROGRESS framework (O'Neill 2014; Ueffing 2009) on inequality issues through the pre-standardised form (Appendix 2). We will collect categories of disadvantaged groups for place, race, occupation, gender, religion, education and socioeconomic aspects.

### Assessment of risk of bias in included studies

Two authors (SG, PG or BB) will independently assess the risks of bias of the included studies. We will carry out this assessment by capturing the information based on the standard criteria described by the Cochrane EPOC Group (EPOC 2013), using section 8 of the pre-standardised form (Appendix 2).

For controlled studies, the assessment will be based on the following:

- Sequence generation
- Allocation concealment
- Blinding of participants, personnel and outcome assessors
- Incomplete outcome data
- Selective outcome reporting
- Other sources of bias

For ITS, the assessment will be based on the following:

- Intervention independent of other changes
- Shape of intervention pre-specified
- Intervention affects outcome data
- Allocation concealment
- Incomplete outcome data
- Selective outcome reporting
- Other sources of bias

For each of these, we will assess the level of risk as follows:

- Low risk of bias: plausible bias unlikely to alter the results
- Unclear risk of bias: plausible bias that raises some doubt about the results
- High risk of bias: plausible bias that seriously weakens confidence in the results

When information is not sufficient to assess the risks, we will contact the study authors and request further details. We will use a table to record the quality assessment of each study with a summary statement.

### Overall risk of bias

Risk of bias for included studies will be documented in a 'Risk of Bias' table for each study in the Characteristics of Included Studies table. We will also summarise results in a 'Risk of bias graph' and a 'Risk of bias' summary.

## Quality of evidence

We will analyse the quality of evidence for the primary outcome using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach (Guyatt 2008). GRADE is the system of rating quality of evidence and grading the strength of recommendations in systematic reviews (Guyatt 2010, Guyatt 2011). Using GRADE, the quality of the evidence is based on a set of items that increase or decrease the quality of evidence. We will classify the quality as 'high', 'moderate', 'low' or 'very low'. The use of GRADE will allow us to systematically and transparently grade quality based on the following factors:
Factors decreasing quality of evidence

- Study limitations
- Inconsistency of results
- Indirectness of evidence
- Imprecision
- Publication bias

Factors increasing quality of evidence

- Large magnitude of effect
- Plausible confounding, which would reduce a demonstrated effect
- Dose-response gradient

Based on these criteria, we will grade each outcome grouping as one of the following:

- High quality - further research is very unlikely to change our confidence in the estimate of effect
- Moderate quality - further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
- Low quality - further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
- Very low quality - any estimate of effect is uncertain

We will create a 'Summary of findings' table to summarise this assessment.

## Measures of treatment effect

We will register and report measures of effect in the same way that the study's authors have reported them. We will standardise measures of effect as mean differences (MD) in natural units or use a standardised scale to allow for comparisons across studies. In the case of interrupted time series analyses, we will use the estimate that is adjusted for changes over time (e.g. regression line). For continuous data, we will present the results as MD if outcomes were measured in the same way between trials. We will use the standardised mean difference (SMD) to combine trials that measured the same outcome, but used different methods. For dichotomous data, we will use risk ratios (RRs) with 95% confidence intervals (CIs).

## Unit of analysis issues

- Cluster-randomised trials:

We will include cluster-randomised trials. If the findings are reported at the individual level, we will report the method used to take into account clustering. In case the clustering effect was not taken into account, we will adjust the sample size to allow for comparison with a sample size of individuals. When possible, we will calculate the intracluster correlation coefficient (ICC) as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011), and we will re-analyse the data. When the data are not available, we will estimate the ICC from another source or from the literature and we will report this. We will also conduct sensitivity analyses to examine the impact of variation in the ICC. In all cases, we will note the approach taken.

- Multiple time points:

We will group outcomes measured at similar points or at similar age points (e.g. children at birth, one year old and three years old) when outcomes are measured on participants at multiple time points and we will use an average effect size to avoid dependence problems. We will use a single measure that is closest to a one-year follow-up when a primary outcome study reports multiple measures at different points in time.

## Dealing with missing data

In case of missing data, we will contact the study's authors by email when contact details are available. If the data cannot be found, we will note this in the study's form and in the 'Risk of bias' table. We will exclude the study from the meta-analysis if it is impossible to obtain the requested information.

## Assessment of heterogeneity

We will consider heterogeneity by examining the study design, participants, setting, intervention duration and age group. If studies reporting the primary outcome are sufficiently similar, we will conduct a meta-analysis. When meta-analysis cannot be conducted,

we will report the results in a narrative way. We will assess statistical heterogeneity in each meta-analysis using the $T^2$, $I^2$ and $Chi^2$ statistics to estimate the percentage of variability that is due to heterogeneity rather than to sampling error or chance and graphically with a forest plot (RevMan 2014). We will consider an $I^2$ value greater than 50% to indicate substantial heterogeneity and we will consider it statistically significant if the P value for the $Chi^2$ test is < 0.1. We will create forest plots and $I^2$ calculations using RevMan 5.3. We will note the result of these statistical tests in the text. Where meta-analysis is undertaken, we will examine forest plots visually for heterogeneity.
We will assess issues of clinical and methodological heterogeneity in tables detailing relevant study-specific characteristics:

- Methods: study design, group assignment, outcome assessment, adjustment for confounders
- Population: setting, age
- Intervention: components, duration
- Context: urban slum/peri-urban slum, baseline mortality and morbidity
- Delivery: primary, secondary or community-based, approach (lay counsellors (e.g. CHWs and peer counsellors) versus professional counselling; personalised versus group intervention)

### Assessment of reporting biases

We will assess the risk of publication bias qualitatively based on the characteristics of the included studies. We will also use a funnel plot to investigate the risk of publication bias by intervention type and outcome measure when this is feasible (at least 10 studies). We will visually examine the funnel plot for asymmetry.
When a study's authors have been contacted and there is no additional data available, if we think that these missing data may introduce a serious bias, we will explore the impact of including such studies in the overall assessment of results by a sensitivity analysis.

### Data synthesis

We will conduct meta-analysis to obtain an overall estimate of the effect of an intervention when more than one study has examined similar interventions using similar methods, been conducted in similar populations and measured similar outcomes. We will then use a fixed-effect analysis for combining data. If there is statistical heterogeneity, we will use a random-effects analysis to produce an overall summary. We will carry out statistical analysis using The Cochrane Collaboration's statistical software, Review Manager 5 (RevMan 2014).
We will carry out a narrative synthesis of the results, grouping our findings by the type of nutritional intervention, study population (by age), context and outcome measured.

### Subgroup analysis and investigation of heterogeneity

We will conduct meta-analysis to provide an estimate of one type of intervention/component on stunting in children. We will be able to conduct the analysis if the interventions share similar methods and outcome measures. If the study design varies between studies, we will favour studies with low risk of bias to conduct the statistical analysis. We will conduct the following subgroup analyses based on:

- the age of the children (younger or older than 24 months);
- nutritional status at baseline (stunting or not);
- location (Asia, Africa, Latin America);
- duration of the intervention (less then or more than 12 months);
- intervention component (nutrition counselling, fortification etc.);
- intervention design (single, combined);
- source of funding.

### Sensitivity analysis

We will carry out sensitivity analysis to examine the effects of removing studies at high risk of bias. We will identify those studies in the assessment with a high or unclear risk of bias.
We will conduct comparative analysis to test for sensitivity of the results of the review by:

- comparing results if we include studies that may have been excluded because only the abstract could be found (where some data and results are provided in the abstract);
- comparing results if we include studies that may have been excluded due to the age range of participants (for example, a study may have included pre-school aged children as well as school aged children);
- comparing results that may have been excluded due to potentially confounding co-interventions (e.g. the co-intervention is only implemented in the intervention group and not in the control group);
- determining whether results differ when studies at high risk of bias are excluded.

We will also carry out sensitivity analysis to examine the effects of funding source on findings. We will compare results with low, medium and high funding sources.

### Summary of findings tables

We will include a 'Summary of findings' table, for the primary outcome and secondary outcomes, including the number of participants and studies for each outcome, a summary of the intervention effect and measure of the quality of the body of evidence assessing evidence quality according to the GRADE Working Group ( Guyatt 2011).

### Review advisory group

Components of the protocol were discussed during two meetings (1 April 2014, 29 September 2014). The review advisory group members are academics with a recognised expertise in urban health, nutrition or vulnerabilities. They have provided comments to ensure that the review will meet its intended goal of assessing the effectiveness of nutritional interventions in a systematic and comprehensive way and that the review will appropriately inform policy.

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* *Indicates the major publication for the study*

# APPENDICES

## Appendix 1. MEDLINE search strategy (PubMed)

**MEDLINE (PubMed) 634 results**

(urban [tiab] OR slum* [tiab] OR shant* [tiab] OR ghetto* [tiab] OR shack* [tiab] OR bidonville* [tiab] OR bustee* [tiab] OR bostee* [tiab] OR bosti* [tiab] OR squat* [tiab] OR "informal settlement" [tiab] OR "informal urban settlement" [tiab] OR barrada [tiab] OR "barrio baja" [tiab] OR "barrio pobre" [tiab] OR taudi* [tiab] OR "irregular settlement" [tiab] OR "informal housing" [tiab] OR favela [tiab] OR "irregular settlement" [tiab] OR basti* [tiab])AND(developing countries[MeSH Terms]OR"poverty areas"[MeSH Terms] OR Africa[MeSH Terms] OR South America[MeSH Terms] OR Asia[MeSH Terms])) AND (child* [tiab] OR infant [MeSH Terms] OR baby [tiab] OR toddler [tiab] OR babies [tiab] OR kid [tiab] OR preschool [tiab] OR "under 5 year" [tiab] OR newborn [tiab] OR neonat* [tiab] OR girl [tiab] OR boy [tiab] OR bambinio [tiab] OR enfant [tiab] OR bébé [tiab] OR "under five year" [tiab]) AND (nutrition [tiab] OR undernourish* [tiab] OR malnutrition[MeSH Terms] OR undernutrition [tiab] OR wasting [tiab] OR stunting [tiab] OR stunted [tiab] OR wasted [tiab] OR kwashiorkor [tiab] OR SAM [tiab] OR GAM [tiab] OR MAM [tiab] OR "growth falter" [tiab] OR "low birth weight" [tiab] OR marasmus [tiab] OR thin [tiab] OR emaciated [tiab] OR "nutritional status" [tiab] OR nutriti*

[tiab] OR malnutrition [tiab] OR "body mass index" [tiab] OR BMI [tiab] OR "short stature" [tiab] OR "weight-for-age" [tiab] OR "height-for-age" [tiab] OR MUAC [tiab] OR "mid upper arm circumference" [tiab] OR anthropometry [tiab] OR "skinfold thickness" [tiab] OR starvation [tiab] OR underweight [tiab] OR malnourishment [tiab] OR "dietary deficiency" [tiab] OR hunger [tiab] OR "food deprived" [tiab] OR "dietary energy requirement" [tiab] OR vitamin* [tiab] OR micronutrient [tiab] OR "community based" [tiab] OR supplementation [tiab] OR fortification [tiab] OR fortified [tiab] OR "school feeding" [tiab] OR "supplementary feeding" [tiab] OR mix* [tiab] OR powder* [tiab] OR supplement* [tiab] OR sachet* [tiab] OR packet* [tiab] OR MNP [tiab] OR "micro nutrient powder" [tiab] OR "formulated food*" [tiab] OR "dietary supplement*" [tiab] OR "formulated fortification diet" [tiab] OR "supplement food*" [tiab] OR "supplement diet" [tiab] OR "ready food*" [tiab] OR "home based treatment" [tiab] OR "nutritional intervention*" [tiab] OR "formulated food*" [tiab] OR sprinkle* [tiab] OR breastfeeding [tiab] OR "nutrition promotion" [tiab] OR "complementary feeding" [tiab] OR "vitamin* supplementation" [tiab] OR "zinc" [tiab] OR multivitamin [tiab] OR "multi vitamin" [tiab] OR lipidbased [tiab] OR "lipid based" [tiab] OR communication [tiab] OR "community nutrition" [tiab] OR "public health nutrition" [tiab] OR project* [tiab] OR program* [tiab]) AND (RCT [tiab] OR "randomized controlled trial" [pt] OR "randomised controlled trial" [tiab] OR "randomized control trial" [tiab] OR "randomised control trial" [tiab] OR "quasi randomised" [tiab] OR "quasi randomized" [tiab] OR "non randomised controlled trial" [tiab] OR "non randomized controlled trial" [tiab] OR "non randomised control trial" [tiab] OR "non randomized control trial" [tiab] OR "historically controlled study" [tiab] OR "interrupted time series" [tiab] OR "before and after study" [tiab] OR "systematic review" [tiab] OR "cohort study" [tiab] OR "cross-sectional study" [tiab] OR "longitudinal study" [tiab] OR "cross-sequential study" [tiab] OR "meta analysis" [tiab] OR "literature review" [tiab])

**Search terms**

| Criteria | Term | Fields | Boolean operators |
|---|---|---|---|
| Urban slum | urban | [tiab] | OR |
| Urban slum | slum* | [tiab] | OR |
| Urban slum | shant* | [tiab] | OR |
| Urban slum | ghetto* | [tiab] | OR |
| Urban slum | shack* | [tiab] | OR |
| Urban slum | bidonville* | [tiab] | OR |
| Urban slum | bustee* | [tiab] | OR |
| Urban slum | bostee* | [tiab] | OR |
| Urban slum | bosti* | [tiab] | OR |
| Urban slum | squat* | [tiab] | OR |
| Urban slum | "informal settlement" | [tiab] | OR |
| Urban slum | "informal urban settlement" | [tiab] | OR |
| Urban slum | barrada | [tiab] | OR |
| Urban slum | "barrio baja" | [tiab] | OR |
| Urban slum | "barrio pobre" | [tiab] | OR |

(*Continued*)

| | | | |
|---|---|---|---|
| Urban slum | taudi* | [tiab] | OR |
| Urban slum | "irregular settlement" | [tiab] | OR |
| Urban slum | "informal housing" | [tiab] | OR |
| Urban slum | favela | [tiab] | OR |
| Urban slum | "irregular settlement" | [tiab] | OR |
| Urban slum | basti* | [tiab]) | AND |
| Geography | (developing countries | [MeSH Terms] | OR |
| Geography | "poverty areas" | [MeSH Terms] | OR |
| Geography | Africa | [MeSH Terms] | OR |
| Geography | South America | [MeSH Terms] | OR |
| Geography | Asia | [MeSH Terms]) | OR |
| Child | child* | [tiab] | OR |
| Child | child | [MeSH Terms] | OR |
| Child | infant | [MeSH Terms] | OR |
| Child | baby | [tiab] | OR |
| Child | toddler | [tiab] | OR |
| Child | babies | [tiab] | OR |
| Child | kid | [tiab] | OR |
| Child | preschool | [tiab] | OR |
| Child | "under 5 year" | [tiab] | OR |
| Child | newborn | [tiab] | OR |
| Child | neonat* | [tiab] | OR |
| Child | girl | [tiab] | OR |
| Child | boy | [tiab] | OR |

(*Continued*)

| | | | |
|---|---|---|---|
| Child | bambinio | [tiab] | OR |
| Child | enfant | [tiab] | OR |
| Child | bébé | [tiab] | OR |
| Child | "under five year" | [tiab] | OR |
| **Intervention category** | **intervention** | | |
| Nutrition | nutrition | [tiab] | OR |
| Nutrition | undernourish* | [tiab] | OR |
| Nutrition | malnutrition | [MeSH Terms] | OR |
| Nutrition | undernutrition | [tiab] | OR |
| Nutrition | wasting | [tiab] | OR |
| Nutrition | stunting | [tiab] | OR |
| Nutrition | stunted | [tiab] | OR |
| Nutrition | wasted | [tiab] | OR |
| Nutrition | kwashiorkor | [tiab] | OR |
| Nutrition | SAM | [tiab] | OR |
| Nutrition | GAM | [tiab] | OR |
| Nutrition | MAM | [tiab] | OR |
| Nutrition | "growth falter" | [tiab] | OR |
| Nutrition | "low birth weight" | [tiab] | OR |
| Nutrition | marasmus | [tiab] | OR |
| Nutrition | thin | [tiab] | OR |
| Nutrition | emaciated | [tiab] | OR |
| Nutrition | "nutritional status" | [tiab] | OR |
| Nutrition | nutriti* | [tiab] | OR |

(*Continued*)

| | | | |
|---|---|---|---|
| Nutrition | malnutrition | [tiab] | OR |
| Nutrition | "body mass index" | [tiab] | OR |
| Nutrition | BMI | [tiab] | OR |
| Nutrition | "short stature" | [tiab] | OR |
| Nutrition | "weight-for-age" | [tiab] | OR |
| Nutrition | "height-for-age" | [tiab] | OR |
| Nutrition | MUAC | [tiab] | OR |
| Nutrition | "mid upper arm circumference" | [tiab] | OR |
| Nutrition | anthropometry | [tiab] | OR |
| Nutrition | "skinfold thickness" | [tiab] | OR |
| Nutrition | starvation | [tiab] | OR |
| Nutrition | underweight | [tiab] | OR |
| Nutrition | malnourishment | [tiab] | OR |
| Nutrition | "dietary deficiency" | [tiab] | OR |
| Nutrition | hunger | [tiab] | OR |
| Nutrition | "food deprived" | [tiab] | OR |
| Nutrition | "dietary energy requirement" | [tiab] | OR |
| Nutrition | vitamin* | [tiab] | OR |
| Nutrition | micronutrient | [tiab] | OR |
| Nutrition | "community based" | [tiab] | OR |
| Nutrition | supplementation | [tiab] | OR |
| Nutrition | fortification | [tiab] | OR |
| Nutrition | fortified | [tiab] | OR |
| Nutrition | "school feeding" | [tiab] | OR |

(*Continued*)

| | | | |
|---|---|---|---|
| Nutrition | "supplementary feeding" | [tiab] | OR |
| Nutrition | mix* | [tiab] | OR |
| Nutrition | powder* | [tiab] | OR |
| Nutrition | supplement* | [tiab] | OR |
| Nutrition | sachet* | [tiab] | OR |
| Nutrition | packet* | [tiab] | OR |
| Nutrition | MNP | [tiab] | OR |
| Nutrition | "micro nutrient powder" | [tiab] | OR |
| Nutrition | "formulated food*" | [tiab] | OR |
| Nutrition | "dietary supplement*" | [tiab] | OR |
| Nutrition | "formulated fortification diet" | [tiab] | OR |
| Nutrition | "supplement food*" | [tiab] | OR |
| Nutrition | "supplement diet" | [tiab] | OR |
| Nutrition | "ready food*" | [tiab] | OR |
| Nutrition | "home based treatment" | [tiab] | OR |
| Nutrition | "nutritional intervention*" | [tiab] | OR |
| Nutrition | "formulated food*" | [tiab] | OR |
| Nutrition | sprinkle* | [tiab] | OR |
| Nutrition | breastfeeding | [tiab] | OR |
| Nutrition | "nutrition promotion" | [tiab] | OR |
| Nutrition | "complementary feeding" | [tiab] | OR |
| Nutrition | "vitamin* supplementation" | [tiab] | OR |
| Nutrition | "zinc" | [tiab] | OR |
| Nutrition | multivitamin | [tiab] | OR |

(*Continued*)

| | | | |
|---|---|---|---|
| Nutrition | "multi vitamin" | [tiab] | OR |
| Nutrition | lipidbased | [tiab] | OR |
| Nutrition | "lipid based" | [tiab] | OR |
| Nutrition | communication | [tiab] | OR |
| Nutrition | "community nutrition" | [tiab] | OR |
| Nutrition | "public health nutrition" | [tiab] | OR |
| Nutrition | project* | [tiab] | OR |
| Nutrition | program* | [tiab] | OR |
| Intervention design | RCT | [tiab] | OR |
| Intervention design | "randomized controlled trial" | [pt] | OR |
| Intervention design | "randomised controlled trial" | [tiab] | OR |
| Intervention design | "randomized control trial" | [tiab] | OR |
| Intervention design | "randomised control trial" | [tiab] | OR |
| Intervention design | "quasi randomised" | [tiab] | OR |
| Intervention design | "quasi randomized" | [tiab] | OR |
| Intervention design | "non randomised controlled trial" | [tiab] | OR |
| Intervention design | "non randomized controlled trial" | [tiab] | OR |
| Intervention design | "non randomised control trial" | [tiab] | OR |
| Intervention design | "non randomized control trial" | [tiab] | OR |
| Intervention design | "historically controlled study" | [tiab] | OR |
| Intervention design | "interrupted time series" | [tiab] | OR |
| Intervention design | "before and after study" | [tiab] | OR |
| Intervention design | "systematic review" | [tiab] | OR |

(*Continued*)

| | | | |
|---|---|---|---|
| Intervention design | "cohort study" | [tiab] | OR |
| Intervention design | "cross-sectional study" | [tiab] | OR |
| Intervention design | "longitudinal study" | [tiab] | OR |
| Intervention design | "cross-sequential study" | [tiab] | OR |
| Intervention design | "meta analysis" | [tiab] | OR |
| Intervention design | "literature review" | [tiab] | |

## Appendix 2. Data extraction pre-standardised form

**Pre-standardised form - nutrition-specific and sensitive interventions for preventing stunting in children (0 to 5 years) living in urban slums**

| | | |
|---|---|---|
| **Study ID:** | **Report ID:** | Date form completed: |
| First author: | Year of study: | Data extractor: |
| Citation: | | |

**1. General Information**

| | |
|---|---|
| Publication type Journal Article c Abstract c Other (specify e.g. book chapter)_____ | |
| Country of study: | |
| Funding source of study: | Potential conflict of interest from funding? Y / N / unclear |

**2. Study Eligibility**

| **Study Characteristics** | | | **Page/ Para/ Figure #** |
|---|---|---|---|
| **Type of study** | c Randomised Controlled Trial (RCT)<br>c Cluster Randomised Controlled Trial (cluster RCT) | c Controlled Before and After (CBA) study<br>· Contemporaneous data collection<br>· Comparable control site<br>· At least 2 x intervention | |

(*Continued*)

| | | | |
|---|---|---|---|
| | | and 2 x control clusters | |
| | c Interrupted Time Series (ITS)<br>· At least 3 time points before and 3 after the intervention<br>· Clearly defined intervention point | c Non randomised controlled trials | |
| | c Historically controlled studies | | |
| | c Quasi randomised | *Does the study design meet the criteria for inclusion?* Yes c No c **Exclude** Unclear c | |
| | Description in text: | | |
| **Participants** | Describe the participants included: Children from low and middle income countries, from birth to five years old living in urban slums in low and middle income countries (LMIC) | | |
| | Are participants defined as a group having specific social or cultural characteristics? | Yes c No c Unclear c<br>Details: | |
| | How is the geographic boundary defined? | Details:<br>Specific location (e.g. state / country): | |
| | *Do the participants meet the criteria for inclusion?* | Yes c No c **Exclude** Unclear c | |
| | | | |

| | | | | |
|---|---|---|---|---|
| **Types of intervention** | Strategies included in the intervention | | | |
| | Focus of the intervention | | | |
| | *Does the intervention meet the criteria for inclusion?* | Yes c No c **Exclude** Unclear c | | |
| **Duration of intervention** | Start date: | Stop date: | Intervention duration: | |
| | *Is the duration of intervention adequate for inclusion?* | Yes c No c **Exclude** Unclear c | | |

(*Continued*)

| | | | |
|---|---|---|---|
| **Types of outcome measures** | List outcomes: | | |
| | Outcome measured at a population level or individual level? | Details: | |
| | *Do the outcome measures meet the criteria for inclusion?* | Yes c No c **Exclude** Unclear c | |
| | | | |

**Summary of Assessment for Inclusion**

| | |
|---|---|
| **Include in review c Exclude from review c** | |
| Independently assessed, and then compared? Yes c No c | Differences resolved Yes c No c |
| Request further details? Yes c No c | Contact details of authors: |
| **Notes:** | |

DO NOT PROCEED IF PAPER EXCLUDED FROM REVIEW

**3. Study details**

| **Study intention** | **Descriptions as stated in the report/paper** | **Page/ Para/ Figure #** |
|---|---|---|
| Aim of intervention | *What was the problem that this intervention was designed to address?* | |
| Aim of study | *What was the study designed to assess? Are these clearly stated?* | |
| Location of study | *Where was the study conducted?*<br>*- Urban slums:*<br>*- Peri urban slums:*<br>*- Country:*<br>*- City:*<br>*- Slum:* | |
| Equity pointer: Social context of the study | *e.g. was study conducted in a particular setting that might target/exclude specific population s? See also Inclusion/exclusion criteria under Methods, below.* | |
| Start and end date of the study | *Identify which elements of planning of the intervention should be included* | |

(*Continued*)

| | | |
|---|---|---|
| Total study duration | | |
| Delivery | *Specify if either community based / primary health care / secondary health care / direct* | |
| Funding: | *Funding source, budget, implementing partner; design, integration within existing government health* | |
| Setting | *whether delivered in humanitarian crisis / disaster or development; including origin of slum, defining characteristics, whether squatter settlement or legal but dilapidated, and whether conditions were improving or worsening* | |

| **Methods** | **Descriptions as stated in the report/paper** | **Page/ Para/ Figure #** |
|---|---|---|
| Method/s of recruitment of participants *(How were potential participants approached and invited to participate? Where were participants recruited from? Does this differ from the intervention setting?)* | | |
| Inclusion/exclusion criteria for participation in study | | |
| Representativeness of sample: Are participants in the study likely to be representative of the target population? | | |
| Total number of intervention groups | | |
| Assumed risk estimate (*e.g. baseline or population risk noted in Background)* | *References:* | |
| Sample size calculation:<br>What assumptions were made?<br>Were these assumptions appropriate? | *(Yes/No/Unclear)* | |
| What was the unit of randomisation?<br>Allocation by individuals or cluster/groups | | |

(*Continued*)

| | | |
|---|---|---|
| What was the unit of analysis?<br>**Is this the same as the unit of randomisation?** | *(Yes/No/Unclear)* | |
| Statistical methods used and appropriateness of these methods | *(Check with your statistician if unsure about appropriateness)* | |

**4. Participants**

| **Participants**<br>*Include if relevant* | **Include information for each group (i.e. intervention and controls) under study** | **Page/ Para/ Figure #** | |
|---|---|---|---|
| · What percentage of selected individuals agreed to participate? | | | |
| · Total number randomised (or total pop. at start of study for NRCTs) | | | |
| · Number allocated to each intervention group (no. of individuals) | | | |
| · For cluster trials, number of clusters, number of people per cluster | | | |
| · Where there any significant baseline imbalances? | Yes c No c Unclear c<br>Details: | | |
| · Number and reason for (and sociodemographic differences of) withdrawals and exclusions for each intervention group | | | |
| · Were patients who entered the study adequately accounted for? | | | |

(*Continued*)

| | | | |
|---|---|---|---|
| · What percentage of patients completed the study? | | | |
| · What percentage of participants received the allocated intervention or exposure of interest? | | | |
| · Is the analysis performed by intervention allocation status (intention to treat) rather than the actual intervention received? Have any attempts been made to impute missing data? | | | |
| · Age (median, mean and range if possible) | | | |
| · Sex | | | |
| · Race/Ethnicity | | | |
| · Principal health problem (incl. stage of illness) | | | |
| · Diagnostic criteria | | | |
| · Co-morbidity | | | |
| · Other socio-demographics (e.g. also consider possible proxies for these e.g. low baseline nutritional status) | | | |
| · PROGRESS categories reported at baseline (indicate letters of those reported: Place of residence, race, occupation, gender, religion, education, SES, social capital) | | | |

(*Continued*)

| | | | |
|---|---|---|---|
| **Subgroups** | *Enter a description of any participant subgroups from this paper to be analysed in the review.* | | |

**5. Intervention Group 1**
*(copy and paste table for each Intervention group)*

| **Group name:** | *(State brief name for this intervention group. )* | **Page/ Para/ Figure #** |
|---|---|---|
| Details of intervention or control condition *(Include if relevant in sufficient detail for replication)* | | |
| · Intervention component (supplementation, fortification,…) | | |
| · Theoretical basis (include key references) | | |
| · Content (list the strategies intended and delivered) | | |
| · Did the intervention include strategies to address diversity/disadvantage? | *Enter a description of any relevant strategies* | |
| · Delivery (e.g. Stages (sequential or simultaneous), timing, frequency, duration, intensity, fidelity - process indicators) | | |
| · Providers (who, number, education/training in intervention delivery, ethnicity etc. if potentially relevant to acceptance and uptake by participants | | |
| · Co-interventions | | |
| Duration of intervention | | |
| Duration of follow-up | | |
| Was sustainability discussed by the authors? Was is a consideration in study development? | | |
| Economic variables<br>i.e. costs of the intervention, and changes in other (e.g. health care) costs as result of intervention[a] | Yes c **List in Outcome section if appropriate**<br>No c Unclear c<br>Details: | |

(*Continued*)

| | | |
|---|---|---|
| Other economic information (from a societal, non-healthcare view - e.g. lost wages, time) | Yes c<br>No c<br>Details: | |
| Resource requirements to replicate intervention (e.g. staff numbers, hours of implementation, equipment?) | | |
| Subgroups | *Enter a description of any intervention subgroups from this report to be analysed in the review.* | |
| What are the moderators/mediators of changes stated in the study? | | |
| Do the authors describe any political or organisational context? | *List relevant dot points* | |
| Were any partnerships referred to? | *List these as dot points* | |
| Was a process evaluation conducted? | *What components were included in the process evaluation? (e.g. dose, frequency, consistency, implemented as intended etc)* | |
| Control/comparison (what information is provided about what the control or comparison group received?) | *Enter a description of what was provided for the control group, if applicable* | |

**6. Outcomes**

*(This table is set up for 2 outcome measure to save spaces, copy and paste table as often as required*)

| **Question** | **Outcome 1** | **Page/ Para/ Figure #** | **Outcome 2** | **Page/ Para/ Figure #** |
|---|---|---|---|---|
| Is there an analytic framework applied (e.g. logic model, conceptual framework)? | | | | |
| Outcome definition (with diagnostic criteria if relevant) | | | | |
| Type of outcome: Is this a modifiable variable (Community level, neighbourhood level, individual level) or desired | | | | |

(*Continued*)

| | | | | |
|---|---|---|---|---|
| health outcome | | | | |
| Time points measured | | | | |
| Time points reported | | | | |
| Is there adequate latency for the outcome to be observed? | | | | |
| Is the measure repeated on the same individuals or redrawn from the population / community for each time point? | | | | |
| Unit of measurement (if relevant) | | | | |
| For scales - upper and lower limits and indicate whether high or low score is good | | | | |
| How is the measure applied? Telephone survey, mail survey, in person by trained assessor, routinely collected data, other | | | | |
| How is the outcome reported? Self or study assessor | | | | |
| Is this outcome/tool validated? | | | | |
| …And has it been used as validated? | | | | |
| Is it a reliable outcome measure? | | | | |
| Is there adequate power for this outcome? | | | | |
| | | | | |

(*Continued*)

| | | | | |
|---|---|---|---|---|
| Were PROGRESS categories analysed by outcome? Indicate the letters of those that outcomes were analysed by (place of residence, race, occupation, gender, religion, education, SES, social capital) | | | | |

**7. Results**

*Copy and paste the appropriate table for each outcome and subgroup at each time point, including baseline*

**For RCT/CCT**

**Dichotomous outcome**

page/para/fig

| | | | | | |
|---|---|---|---|---|---|
| Comparison | | | | | |
| Outcome | | | | | |
| Subgroup | | | | | |
| Time point | | | | | |
| **Results** | **Intervention** | | **Comparison** | | |
| | Events | No. participants | Events | No. participants | |
| | | | | | |
| No. of missing participants and reasons | | | | | |
| Any other results reported | | | | | |
| Reanalysis required? (specify - (e.g. correlation adjustment) | | | | | |
| Reanalysis possible? | *yes/no/unclear* | | | | |
| Reanalysed results | | | | | |

**For RCT/CCT**

**Continuous outcome** page/para/fig

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Comparison | | | | | | | |
| Outcome | | | | | | | |
| Subgroup | | | | | | | |
| Time point | | | | | | | |
| Post-intervention or change from baseline? | | | | | | | |
| **Results** | **Intervention** | | | **Comparison** | | | |
| | Mean | SD (or other variance) | No. participants | Mean | SD (or other variance) | No. participants | |
| | | | | | | | |
| No. missing participants and reasons | | | | | | | |
| Any other results reported | | | | | | | |
| Reanalysis required? (specify) | | | | | | | |
| Reanalysis possible? | *yes/no/unclear* | | | | | | |
| Reanalysed results | | | | | | | |

**For RCT/CCT**
**Generic inverse variance method**
Page/para/figure

| | | |
|---|---|---|
| Comparison | | |
| Outcome | | |
| Subgroup | | |
| Time point | | |

(*Continued*)

| Results | Effect estimate | SE (or other variance) | Intervention no. | Control no. | |
|---|---|---|---|---|---|
| | | | | | |
| No. missing participants and reasons | | | | | |
| Any other results reported | | | | | |
| Reanalysis required? (specify) | | | | | |
| Reanalysis possible? | *yes/no/unclear* | | | | |
| Reanalysed results | | | | | |

**For quasi RCT**
Page/para/figure

| Comparison | | | | | |
|---|---|---|---|---|---|
| Outcome | | | | | |
| Subgroup | | | | | |
| Time point | | | | | |
| Results | Effect estimate | SE (or other variance) | Intervention no. | Control no. | |
| | | | | | |
| No. missing participants and reasons | | | | | |
| Any other results reported | | | | | |
| Reanalysis required? (specify) | | | | | |
| Reanalysis possible? | *yes/no/unclear* | | | | |
| Reanalysed results | | | | | |

**For non RCT**
Page/para/figure

| | | | | | |
|---|---|---|---|---|---|
| Comparison | | | | | |
| Outcome | | | | | |
| Subgroup | | | | | |
| Time point | | | | | |
| Results | Effect estimate | SE (or other variance) | Intervention no. | Control no. | |
| | | | | | |
| No. missing participants and reasons | | | | | |
| Any other results reported | | | | | |
| Reanalysis required? (specify) | | | | | |
| Reanalysis possible? | *yes/no/unclear* | | | | |
| Reanalysed results | | | | | |

**For CBA**
Page/para/fig

| | | |
|---|---|---|
| Comparison | | |
| Assignment | How were control and treatment groups selected?? Is there likely to be an effect if these were the opposite way? | |
| | Contemporaneous data collection? | |
| Outcome | | |
| Subgroup | | |
| Time point | | |
| Post-intervention or change from baseline? | | |

(*Continued*)

| | Intervention | Comparison | |
|---|---|---|---|
| No. participants measured | | | |
| No. missing participants and reasons | | | |
| Baseline result (with variance measure) | | | |
| Post-intervention results (with variance measure) | | | |
| Change (Post - baseline) (with variance measure) | | | |
| Difference in change (intervention - control) (with variance measure) | | | |
| Any other results reported | | | |
| Reanalysis required? (specify) | | | |
| Reanalysis possible? | *yes/no/unclear* | | |
| Reanalysed results | | | |

**For ITS**
**Generic inverse variance method** Page/para/fig

| | | |
|---|---|---|
| Comparison | | |
| Outcome | | |
| Subgroup | | |
| Length of time points measured | | |
| Snapshot or interval measured | | |
| No. participants measured | | |

(*Continued*)

| | | | | | | |
|---|---|---|---|---|---|---|
| No. missing participants and reasons | | | | | | |
| | Pre-intervention | | | Post-intervention | | |
| No. of time points measured | | | | | | |
| Mean value (with variance measure) | | | | | | |
| Difference in means (post - pre) | | | | | | |
| Percent relative change | | | | | | |
| Result reported by authors (with variance measure) | | | | | | |
| Reanalysis required? (specify) | | | | | | |
| Reanalysis possible? | *yes/no/unclear* | | | | | |
| Individual time point results | | | | | | |
| Read from figure? | *yes/no* | | | | | |
| Reanalysed results | Change in level | SE | Change in slope | | SE | |
| | | | | | | |
| | | | | | | |

**For historically controlled studies**
Page/para/fig

| | | | |
|---|---|---|---|
| Comparison | | | |
| Outcome | | | |
| Subgroup | | | |
| Length of time points measured | | | |
| Snapshot or interval measured | | | |
| No. participants measured | | | |
| No. missing participants and reasons | | | |
| | Pre-intervention | Post-intervention | |
| No. of time points measured | | | |
| Mean value (with variance measure) | | | |
| Difference in means (post - pre) | | | |
| Percent relative change | | | |
| Result reported by authors (with variance measure) | | | |
| Reanalysis required? (specify) | | | |
| Reanalysis possible? | *yes/no/unclear* | | |
| Individual time point results | | | |

(*Continued*)

| | | | | | |
|---|---|---|---|---|---|
| Read from figure? | *yes/no* | | | | |
| Reanalysed results | Change in level | SE | Change in slope | SE | |
| | | | | | |

**Other relevant information**

| | |
|---|---|
| Were outcomes relating to harms/unintended effects of the intervention described? Include any data for these in the outcomes tables above | |
| Potential for author conflict *i.e. evidence that author or data collectors would benefit if results favoured the intervention under study or the control* | |
| Key conclusions of the study authors | |
| Could the inclusion of this study potentially bias the generalisability of the review? Equity pointer: Remember to consider whether disadvantaged populations may have been excluded from the study | |
| Is there potential for differences in relative effects between advantaged and disadvantaged populations? (e.g. are children from lower income families less likely to wear bicycle helmets) | |
| Are interventions likely to be aimed at the disadvantaged? (e.g. school meals aimed at poor children) | |

(*Continued*)

| | |
|---|---|
| Issues affecting directness (*Note any aspects of population, intervention, etc. that affect this study's direct applicability to the review question)* | |
| Recommendations | |
| Limitations | |
| References to other relevant studies | |
| Additional notes by review authors | |
| Correspondence required for further study information (from whom, what and when) | |

8. **Risk of bias assessment**

| Domain | Review authors' judgement* | Description | Page/ Para/ Figure # |
|---|---|---|---|
| **Was the allocation sequence adequately generated?** | **Yes / No / Unclear** | ***Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.*** | |
| **Was allocation adequately concealed?** | **Yes / No / Unclear** | ***Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment.*** | |
| **Were baseline outcome measurements similar?** | **Yes/No/Unclear** | ***Note whether baseline outcome measurements were reported and whether there were any important differences between groups. If there were important differences between groups, note whether appro-*** | |

(*Continued*)

| | | | |
|---|---|---|---|
| | | ***priate adjusted analysis was performed to account for this.*** | |
| **Were baseline characteristics similar?** | **Yes/No/Unclear** | ***Note whether baseline characteristics were reported and whether there were any important differences between groups.*** | |
| **Were incomplete outcome data adequately addressed?** ***Assessments should be made for each main outcome (or class of outcomes).*** | **Yes / No / Unclear** | ***Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants) , reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors.*** | |
| **Was knowledge of the allocated intervention adequately prevented during the study?** ***Separate assessments should be made for relevant groups of people involved in the study i. e. participants, outcome assessors, investigators, data assessors etc*** | **Yes / No / Unclear** | ***Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective, or whether blinding was appropriate.***<br>· Participants - yes, no, unclear *[record supporting statement from study].*<br>· Investigators - yes, no, unclear *[record supporting statement from study].*<br>· Outcomes assessors - yes, no, unclear *[record supporting statement from study].*<br>Data assessors - yes, no, unclear *[record supporting statement from study].* | |
| **Was the study adequately protected against contamination?** | **Yes/No/Unclear** | ***State whether and how the possibility of contamination was minimised by the study de-*** | |

(*Continued*)

| | | | |
|---|---|---|---|
| | | ***sign/implementation.*** | |
| **Are reports of the study free of suggestion of selective outcome reporting?**<br>***Assessments should be made for each main outcome (or class of outcomes).*** | **Yes / No / Unclear** | ***State how the possibility of selective outcome reporting was examined by the review authors, and what was found.*** | |
| **Other sources of bias**<br>. | **Yes / No / Unclear** | ***State any important concerns about bias not addressed in the other domains in the tool.*** | |
| **ITS: Was the intervention independent of other changes?** | **Yes/No/Unclear** | ***Describe whether or not the intervention occurred independently of other changes over time and whether or not the outcomes may have been influenced by other confounding variables/historic events during the study period.*** | |
| **ITS: Was the shape of the intervention effect pre-specified?** | **Yes/No/Unclear** | ***State whether or not the point of analysis was the point of intervention. If not, describe whether a rationale for the shape of the intervention effect was given by the study authors.*** | |
| **ITS: Was the intervention unlikely to affect data collection?** | **Yes/No/Unclear** | ***Describe whether or not the intervention was likely to affect data collection and what the potential impact might have been.*** | |
| **ITS: Was knowledge of the allocated interventions adequately prevented during the study?**<br>***Separate assessments should be made for relevant groups of people involved in the study i. e. participants, outcome assessors, investigators, data assessors etc*** | **Yes/No/Unclear** | ***Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective, or whether blinding was appropriate.***<br>· Participants - yes, no, unclear *[record supporting statement from study].*<br>· Investigators - yes, no, unclear | |

(*Continued*)

| | | | |
|---|---|---|---|
| | | *[record supporting statement from study].*<br>· Outcomes assessors - yes, no, unclear *[record supporting statement from study].*<br>Data assessors - yes, no, unclear *[record supporting statement from study].* | |
| **ITS: Was incomplete outcome data adequately addressed?** ***Assessments should be made for each main outcome (or class of outcomes).*** | **Yes/No/Unclear** | ***Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors.*** | |
| **ITS: Was the study free from selective reporting?** | **Yes/No/Unclear** | ***State how the possibility of selective outcome reporting was examined by the review authors, and what was found.*** | |
| **ITS: Was the study free from other risks of bias?** | **Yes/No/Unclear** | ***State any important concerns about bias not addressed in the other domains in the tool.*** | |

* Note: For each section above 'Yes' indicates a 'low risk of bias'; 'No' indicates a 'high risk of bias'; 'Unclear' indicates an 'uncertain risk of bias'. When entering the data into RevMan, the options to choose from will be 'Low', 'High' and 'Unclear'

**9. Results**

Comparison:

Outcome:

Subcategory:

| **Treatment group:** | | **Control group:** | |
|---|---|---|---|
| Observed (n) | total (N) | observed (n) | total (N) |
| | | | |

| | Treatment group: | Control group: |
|---|---|---|
| Total randomised | | |
| excluded* | | |
| Observed | | |
| lost to follow up* | | |

*Reasons for loss/exclusion:
Subcategory:

| Treatment group: | | Control group: | |
|---|---|---|---|
| Observed (n) | total (N) | observed (n) | total (N) |
| | | | |

| | Treatment group: | Control group: |
|---|---|---|
| Total randomised | | |
| excluded* | | |
| Observed | | |
| lost to follow up* | | |

*Reasons for loss/exclusion
Costs associated with the intervention can be linked with provider or participant outcomes in an economic evaluation (depends on the type of economic evaluation)

## WHAT'S NEW

| Date | Event | Description |
|---|---|---|
| 28 August 2018 | Amended | Title amended to include 'in low and middle-income countries (LMIC)' to reflect inclusion criteria |

## CONTRIBUTIONS OF AUTHORS

SG drafted the protocol. All authors contributed to its finalisation by providing comments and reviews.

## DECLARATIONS OF INTEREST

None.

## SOURCES OF SUPPORT


### Internal sources

- None, Other.

### External sources

- None, Other.